Premarket Notification (510(k)) Summary

3M

Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person:	Suzanne Leung, Ph.D., RAC Regulatory Affairs Manager
Phone Number:	(651) 575-8052
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Date of Summary:	March 14, 2013

Device Name and Classification:

Common or Usual Name:	Sterilization Biological Indicator
Proprietary Name:	3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack 3M Attest™ 41482V Super Rapid 5 Steam-Plus Challenge Pack
Classification Name:	Indicator, Biological Sterilization Process (21 CFR § 880.2800(a))
Product Code:	FRC
Product Class:	Class II

Predicate Devices:

3M Attest™ Steam-Plus Pack, formerly ATI® Disposable Biological-Plus Test Pack cleared under K925496, acquired by 3M

3M Attest™ 1492V Super Rapid Readout Biological Indicator for Steam and 3M Attest™ 490 Auto-reader (K121484)

Description of Device:

The 3M Attest™ 1496V Super Rapid Readout Steam and 41482V Super Rapid 5 Steam-Plus Challenge Packs are specifically designed to qualify or routinely challenge 270°F (132°C) and 275°F (135°C) dynamic-air-removal (pre-vacuum) steam sterilization cycles in healthcare facilities.

Similarities to the predicate device

The 1496V and 41482V Challenge Packs are similar in design to the predicate device the 3M Attest™ Steam-Plus Pack. The packs consist of multiple layers of medical index cards, some of which are die-cut to contain monitoring products. The packs are overwrapped and secured with a label. The Challenge Packs and the predicate device all contain a biological indicator. The 41482V Challenge Pack and the predicate device also contain a SteriGage™ chemical integrator. The SteriGage™ integrator offers an immediate Accept/Reject reading that allows for implant load early release in emergency situations as defined in AAMI ST-79. Each Challenge Pack has a chemical process indicator on the outside of the device that changes from yellow to brown or darker when exposed to steam.

Differences from the predicate device

Each 1496V test pack contains an Attest™ 1492V Super Rapid Biological Indicator (1492V SRBI) while the 41482V Super Rapid 5 Steam-Plus Challenge Pack contains a 1492V SRBI and a SteriGage™ steam chemical integrator. The predicate device contains an Attest™ 1262 Biological Indicator with a visual pH color change result at 48 hours and a SteriGage™ steam chemical integrator. The 1492V SRBI is specifically designed for a rapid fluorescent result when used in conjunction with the 3M Attest™ 490 Auto-reader. A fluorescence change indicates a steam sterilization process failure. Attest™ 1492V SRBI controls are provided with the Challenge Packs.

Similarities and Differences between Challenge Packs and Predicate Device

	Predicate Device Attest™ Steam-Plus Pack	**Attest™ 1496V Challenge Pack**	**Attest™ 41482V Challenge Pack**
General Design	Layers of medical index cards, some of which are die-cut to contain indicators, overwrapped and secured with a label.	Same as Predicate	Same as Predicate
Biological Indicator	Attest™ 1262 Biological Indicator (48 hr visual pH color change result)	Attest™ 1492V Biological Indicator (1 hour fluorescent result)	Attest™ 1492V Biological Indicator (1 hour fluorescent result)
Chemical Integrator	SteriGage™ Chemical Integrator	No Chemical Integrator	SteriGage™ Chemical Integrator
External Chemical Process Indicator	Yellow to brown color change when exposed to steam	Same as Predicate	Same as Predicate

Indications for Use:

Use the 3M Attest™ Super Rapid Readout Steam Challenge Pack 1496V and the 3M Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V in conjunction with the 3M Attest™ Auto-reader 490 to qualify or monitor dynamic-air-removal (pre-vacuum) steam sterilization cycles of 270°F (132°C) at 4 minutes and 275°F (135°C) at 3 minutes.

The 3M Attest™ Super Rapid Readout Biological Indicator 1492V contained in the challenge pack provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Testing was conducted on the indicators and the challenge packs following the FDA guidance and standards below:

- FDA's *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions;* October 4, 2007
- FDA's *Premarket Notification [510(k)] Submissions for Chemical Indicators: Guidance for Industry and FDA Staff,* December 19, 2003
- ANSI/AAMI/ISO 11138-1:2006/(R)2010 *Sterilization of health care products – Biological indicators – Part 1: General requirements*
- ANSI/AAMI/ISO 11138-3: 2006/(R)2010 *Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes*
- ANSI/AAMI/ISO 11140-1:2005/(R)2010 *Sterilization of health care products – Chemical indicators, Part 1: General requirements*
- ANSI/AAMI/ISO 18472:2006 *Sterilization of health care products – Biological and chemical indicators: Test equipment*
- United States Pharmacopeia, Chapter <1035> *Biological Indicators for Sterilization* and Chapter <55> *Biological Indicators – Resistance Performance Tests.*
- ANSI/AAMI ST-79: 2010, A1:2010 and A2:2011, *Comprehensive guide to steam sterilization & sterility assurance in health care facilities*

Multiple lots of 3M Attest™ Super Rapid Challenge Packs were prepared containing multiple lots of 1492V Super Rapid BIs and SteriGage™ chemical integrators. The Challenge Packs were evaluated against performance requirements below.

Summary of Nonclinical Testing

Challenge Pack Testing	Acceptance Criteria	Result
Resistance of the Challenge Pack as compared to AAMI towel pack	Challenge Pack is at least as resistant as the biological indicator AAMI towel pack recommended by ANSI/AAMI ST-79: 2010, A1:2010 and A2:2011	Pass
Resistance of the Pack as compared to the Biological Indicator or Chemical Integrator alone	Pack provides a greater resistance than the Biological Indicator or Chemical Integrator alone	Pass
Chemical Process Indicator	Chemical Process Indicator on the Challenge Pack label changes from yellow to brown or darker upon exposure to steam	Pass
Characteristics of Biological Indicator	Challenge Packs contain a biological indicator with *Geobacillus stearothermophilus* (ATCC™ 7953) at a population ≥ 10^6 spores that complies with FDA's *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions;* October 4, 2007, ANSI/AAMI/ISO 11138-1:2006/(R)2010 and ANSI/AAMI/ISO 11138-3: 2006/(R)2010	Pass
Characteristics of Chemical Integrator (41482V only)	Challenge Packs contain a chemical integrator that complies with FDA's Guidance for Chemical Indicators FDA's *Premarket Notification [510(k)] Submissions for Chemical Indicators: Guidance for Industry and FDA Staff,* December 19, 2003 and ANSI/AAMI/ISO 11140-1:2005/(R)2010, Class 5	Pass

The results of these evaluations showed that the 3M Attest™ 1496V and 41482V Super Rapid Challenge Packs present a challenge to the sterilization process equivalent to the biological indicator AAMI towel pack recommended by ANSI/AAMI ST-79 *Comprehensive guide to steam sterilization & sterility assurance in health care facilities.*

Conclusion

The 3M Attest™ 1496V and 41482V Super Rapid Challenge Packs and the 3M Attest™ 490 Auto-reader meet all applicable voluntary performance standards and are substantially equivalent to the predicate device in terms of their intended use, physical properties and technological characteristics. There are no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 15, 2013

Suzanne Leung, Ph.D., RAC
Regulatory Affairs Manager
3M Company
3M Center, Building 275-5W-06
ST. PAUL MN 55144-1000

Re: K121593
Trade/Device Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack
3M Attest™ 41482V Super Rapid 5 Steam-Plus Challenge Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: March 1, 2013
Received: March 4, 2013

Dear Dr. Leung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K121593

Device Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack
3M Attest™ 41482V Super Rapid 5 Steam-Plus Challenge Pack

Indications for Use:

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Prescription Use _____ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121593